## LAW OFFICES

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> > April 7, 2005

Via Federal Express

Office of Nutritional Products, Labeling, And Dietary Supplements (HFS-820) Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, Maryland 20740-3835

Re: New Dietary Ingredient Notification:

Zeaxanthin Purified Concentrate from Marigold

41322

Dear Sir or Madam:

Enclosed please find an original and two copies of the 75 day Premarket Notification for the new dietary ingredient Zeaxanthin Purified Concentrate from marigold (ZPC) as required by Section 413(a)(2) of the Food, Drug, and Cosmetic Act (FDC Act) and a regulation issued by the Food and Drug Administration (FDA) at 21 CFR Section 190.6 ZPC is a dietary supplement ingredient as defined by Section 201(ff)(1)(C)(F) of the FDC Act.

Please note that pursuant to 21 CFR Section 20.61, we request that Attachments 1 identified as the ZPC production process, Attachments 23A and B, identified as the Ames Report, Attachment 24, identified as 28-day Subchronic Toxicity Report, and Attachment 25, identified as Acute Oral Toxicity Report are considered confidential information.

Please note that the 28-day Subchronic Toxicity Report is an unauditied draft report which will be supplemented with an additional filing when the final report is available.

ZPC is a dietary ingredient that will provide a new source of Zeaxanthin to supplement the diet. The submission contains a table of

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contents that will allow quick reference to the attached documents and scientific studies. Within 50 days after receipt of our 75 day premarket notification by FDA, we intend to call the agency to discuss the review status of the notification.

We appreciate your attention to this submission. If you should have any questions regarding the notification, please contact me.

Sincerely,

W. Patrick Noonan

**Enclosures**